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Congress of the United States
House of Representatives
Washington, DC 20515-2306

March 5, 2019

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HOUSE REPUBLICAN STEERING

REPUBLICAN WHIP TEAM

DEPUTY WHIP TEAM

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

We're writing to you regarding a timely and important issue facing medical device manufacturers located in Minnesota and throughout the country.

Last week, a key source of sterilization for many manufacturers was abruptly shut down by state-level environmental authorities due to environmental concerns. These concerns are very alarming and should continue to be addressed with a focus on the health and well-being of the residents in the immediate area. The sudden and unanticipated closing of this facility, however, is posing significant challenges to the supply of life-saving medical devices for patients.

The now-shuttered sterilization source was a preferred site for medical device manufacturers of all sizes, due to its large and significant medical device work and its known compliance to FDA and European Union standards. The loss of this site is particularly acute for small and medium sized manufacturers. Due to their smaller production volumes, this site was their only qualified and validated sterilization source.

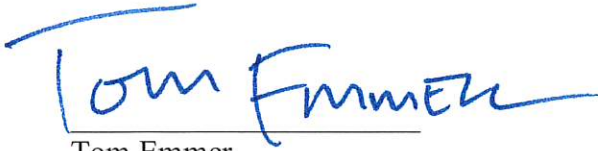
The process to change the source of sterilization is complex and typically takes anywhere from three to six months to complete. Since this site shut-down was unexpected, manufacturers have as little as one or two months of supply ready and available. Without prompt action, patients could soon be facing a shortage of life-saving and quality of life improving medical devices.

Patients should not have to suffer for a mistake they had no part in making. We are asking you to immediately take any and all action needed to prevent this potentially tragic scenario, while continuing to ensure the safety and effectiveness of these devices. By acting swiftly, you can provide certainty to patients throughout the country that there will be no interruption to the supply of medical devices they need. Health care and industry experts across the country and throughout Minnesota's medical alley stand ready and willing to work with you and your agency to design a solution that accomplishes this.

Thank you for your consideration.

Sincerely,

Congress of the United States
Washington, DC 20515



Tom Emmer
Member of Congress



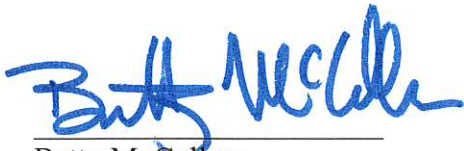
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